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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,073	06/29/2005	Yoshiyuki Ishikura	47237-0561-00 (216942)	4059
55694 7590 06/02/2011 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER PURDY, KYLE A	
			ART UNIT 1611	PAPER NUMBER
			NOTIFICATION DATE 06/02/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbr.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/541,073	<b>Applicant(s)</b> ISHIKURA ET AL.	
	<b>Examiner</b> KYLE PURDY	<b>Art Unit</b> 1611	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-6 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-6 and 29-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)   | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10 pages (5/26/2010, 7/2/2010, 7/21/2010, 8/11/2010, 10/19/2010, 12/6/2010, 1/19/2011, 1/26/2011 and 3/21/2011)</u> | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/27/2011 has been entered.

### ***Status of Application***

2. The Examiner acknowledges receipt of the amendments/arguments filed on 11/27/2009 wherein claim 29 has been amended.

3. Claims 3-6 and 29-33 are presented for examination on the merits. The following rejections are made.

### ***Response to Applicants' Arguments***

4. Applicants arguments filed 11/27/2011 regarding the objection to the specification's abstract have been considered and are persuasive. The objection has been overcome in view of Applicants submission of a substitute declaration.

5. Applicants arguments filed 11/27/2011 regarding the rejection of claims 4 and 29 made by the Examiner under 35 USC 102(e) over Akimoto et al. (US 2004/0266874) have been fully considered and they are found persuasive. The incorporation of the limitations of claims 30, 31 and 33 into claim 29 overcomes the anticipation rejection.

6. Applicants arguments filed 11/27/2011 regarding the rejection of claims 3-6 and 29-32 made by the Examiner under 35 USC 103(a) over Akimoto et al. (US 2004/0266874), evidenced

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by Strub and Nucleus Medical have been fully considered and they are found persuasive, as Akimoto is excluded under 103(c).

**New Rejections, Necessitated by 103(c)**  
***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**8. Claims 4 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakai et al. (JP 09030962; published 2/4/1997, machine translation provided).**

9. Sakai is directed to the use of medical composition containing triglycerides containing fatty acids useful in decreasing blood cholesterol and prevention/treatment of arteriosclerosis and ischemic heart disease (see [0006]; see instant claims 29-31). The triglyceride may be substituted with a long chain polyunsaturated fatty acid (see [0011]) such as arachidonic acid ([0021]). The triglycerides may be derived from microorganisms like *Mucor* and *Aspergillus* (see [0029]; see instant claim 4).

10. With respect to the instant claims recited purpose for treating a drop of the elasticity of blood vessels associated with aging in an individual, this is an inherent property of the method of administering a triglyceride having arachidonic acid to patients having arteriosclerosis and/or ischemic heart disease. The fact that Sakai teach administering the same composition to the same patient population means that the composition will necessarily have the claimed effect, i.e. treating a drop of the elasticity of blood vessels associated with aging in an individual. Under the

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principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art method. When the prior art method is the same as a method described in the specification for carrying out the claimed method, it can be assumed the method will inherently perform the claimed process. See *In re Best*, 562 F. 2d, 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and *Ex parte Novitski*, 26 USPQ 2d 1389 (Bd. Pat. App. & inter. 1993). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference. See *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67, USPQ2d 1664, 1668 (Fed. Cir. 2003). See also *Toro Co. v. Deere & Co.* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004).

11. Therefore, Sakai anticipates the instantly rejected claims.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**14. Claims 3-6 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. (JP 09030962; published 2/4/1997, machine translation provided) in view of Golfetto et al. (Nutr. Neurosci., 2001, 4(1), 75-79, abstract relied upon).**

15. Sakai is directed to the use of medical composition containing triglycerides containing fatty acids useful in decreasing blood cholesterol and prevention/treatment of arteriosclerosis and ischemic heart disease (see [0006]; see instant claims 29-31). The 2-position of the triglyceride may be substituted with more than 50 mol % of the total amount of long chain polyunsaturated fatty acid (see [0011]). Exemplified polyunsaturated fatty acids include arachidonic acid (see [0021]; see instant claims 3, 5 and 29). Further, upon reaction of the long chain polyunsaturated fatty acid in the 2-position of the glyceride backbone, an arbitrary fatty acid other than long chain polyunsaturated fatty acid is distributed at random or un-random in the 1<sup>st</sup> place and the 3<sup>rd</sup> place (i.e. 1,3-position) with more than 60 mol % of long chain polyunsaturated fatty acid (see [0020]). Possible 1, 3-position fatty acids include medium-chain fatty acids such as caproic acid, caprylic acid, capric acid, lauric acid, and so on (see [0022]; see instant claim 6). The triglycerides may be obtained from microorganisms like *Mucor* and *Aspergillus* (see [0029]). As discussed above, the fact that Sakai teach administering the same composition to the same patient population means that the composition will necessarily have the claimed effect, i.e. treating a drop of the elasticity of blood vessels associated with aging in an individual.

16. Sakai fails to teach administering the composition to an individual suffering from cerebral hemorrhage.

17. Golfetto is directed to the treatment of hemorrhagic stroke with arachidonic acid.

Golfetto teaches administering arachidonic acid to a subject with a large hemorrhagic area and a history of ischemic heart disease, and subsequently recovered very well according to the Barthel Scale. Thus, it would be obvious to provide the triglyceride having arachidonic acid as a component fatty acid to treat a subject with cerebral hemorrhage.

18. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sakai and Golfetto with a reasonable expectation for success in arriving at a method of treating a drop in blood vessel elasticity associated with aging in an individual, comprising administering an effective amount of a triglyceride having arachidonic acid as a component fatty acid wherein the individual suffers from arteriosclerosis, ischemic cardiac disease or cerebral hemorrhage. While Sakai fails to teach using their arachidonic substituted triglyceride for the treatment of cerebral hemorrhage, it would have been obvious to do so in view of Golfetto which teaches administration of arachidonic acid is useful for treating cerebral hemorrhage and ischemic heart disease. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

**19. Claims 3-6 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akimoto et al. (US WO03/013497) evidenced by English equivalent US 2004/0266874, Strub (Southern Medical Journal, Volume 96, Number 4, pages 363-366; of record) and Nucleus Medical (<http://ebSCO.smartimagebase.com/displaymonograph.php?MID=138>)**

20. Akimoto teaches a method of administering a composition comprising a triglyceride having arachidonic acid as a constituent fatty acid to ameliorate the diseases caused by decreased brain function such as cerebrovascular dementia (see Examples 3 and 4; see instant claim 29). Akimoto teaches that the compound used in their method is obtained from *Mortierella alpine* (see Example 1; see instant claim 4). Akimoto teaches that the compositions can be useful for treating cerebrovascular dementia. The definition of cerebrovascular dementia (Strub, "Vascular Dementia," 2003, Southern Medical Journal, Volume 96, Number 4, pages 363-366, Historical Perspective Section) is an arteriosclerotic dementia in which the arteriosclerosis (hardening of the arteries) of the brain would result in a subsequent narrowing of the arteries, resulting in multiple small vessel infarcts that manifest themselves in dementia of the subject (see instant claim 30). Akimoto teaches the compound having arachidonic acid as the constituent fatty acid is an alcohol ester or a triglyceride or a phospholipid (see claim 2). Example 7 teaches the triglyceride in a composition at about 32% by weight (see instant claim 3). Moreover, Akimoto discloses a triglyceride compound having arachidonic acid as a constituent fatty acid as being extracted from multiple microorganisms, such as *Mortierella alpine* (see claim 4 and [0032]). The location and the identity of the medium-chain fatty acids are also taught by Akimoto. See [0038]) which states that the triglycerides have fatty acids bound at the 1,3-position and arachidonic acid is bound at the 2-position can be from 5 mol % and above, up to 30 mol % (see instant claim 5). Preferred fatty acids have from 6 to 12 carbon atoms (see [0032]; see instant claim 6).



21. Akimoto fails to positively teach a method of administering the compound to an individual having an ischemic cardiac disease such as a myocardial infarction, arteriosclerosis or a cerebral hemorrhage (i.e. stroke).

22. Regardless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Akimoto with a reasonable expectation for success in arriving at a method of administering a triglyceride having an arachidonic acid component to a person suffering from an ischemic cardiac disease or arteriosclerosis. While Akimoto does not specifically teach the method as being administered to a subject with an ischemic cardiac disease, it would have been obvious to an ordinary skilled artisan to do such because Akimoto states that such compounds possesses utility in treating cerebral dementia which is characterized by arteriosclerosis and minor infarcts in the vessel walls. And although Akimoto does not states that the infarction is an myocardial infarction, this however, does not lend any patentable matter to the instant claims. An infarction is an infarction, regardless of the location of the infarction. Whether it is in a vessel distant from the heart or is actually on the heart itself is immaterial to the final result. With respect to treating a population afflicted with a cerebral hemorrhage, this is obvious. As it is known that cerebral arteriosclerosis leads to hemorrhagic strokes (i.e. cerebral hemorrhage) which can sometimes be fatal (see Nucleus Medical), one of ordinary skill would expect the administration of arachidonic triglyceride to effectively treat such a condition because, as already noted, the compound is disclosed by the art as useful in treating diseases characterized by arteriosclerosis of cerebral blood vessels. Thus, one would be motivated to administer the compound to an individual with a cerebral hemorrhage because such as a condition, it is characterized by arteriosclerosis formation. Thus, by administering the

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compounds to such a subject would improve the cerebral blood vessels health and decrease the likelihood that the cerebral hemorrhage will be fatal. Therefore, a method of treating a population characterized by their possessing arteriosclerosis, an ischemic disease or a cerebral hemorrhage with a triglyceride with arachidonic acid component is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

### ***Conclusion***

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/  
Examiner, Art Unit 1611  
May 13, 2011

/Allison M. Ford/  
Primary Examiner, Art Unit 1653

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